REMARKS

The above claim amendments are submitted along with the following remarks to be fully responsive to the outstanding Office Action mailed September 29, 2005. It is further submitted that this response is timely filed within the three month shortened statutory period. Reconsideration of all outstanding grounds of objection and rejection and allowance of the subject application are respectfully requested.

Claims 43 and 45-47 are objected to because they depend on claim 41, which claim was not originally filed. In response, claims 43 and 45-47 have been amended to change their dependencies on claim 40 and 41 to instead depend only from claim 42, which is the independent claim that was erroneously numbered as claim 41 in the originally submitted claim set. Thus, claims 43-51 now depend directly or indirectly only from claim 42. However, in order to claim the same subject matter as the originally filed multiple dependent claims, a new set of dependent claims 58-66 is added by the present amendment, which depend only from independent claim 40. These claims contain identical subject matter to that of the dependent claims 43-51, except that these claims depend from only claim 40, instead of depending from multiple independent claims. Thus, no new subject matter is added and the objection to claims 43 and 45-47 has been overcome. In addition, claims 40 and 42 were both amended to correct a typographical error of the inadvertent omission of the word "of" in the originally submitted claims.

Applicants note with appreciation the Examiner's indication of the allowability of claim 42. Because claims 43-51 all depend either directly or indirectly from claim 42, as explained above, these claims are likewise believed allowable.

In the Office Action, claims 40, 43-49, and 51 were rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,830,551 (Uchigaki et al.). Due to the submission of new claims 58-66 as claims that depend from claim 40 (instead of claims 43-51, as explained above), the rejection is discussed below as applying to claims 40, 58-64, and 66.

As amended, claim 40 recites a method for determining the concentration of at least one target constituent contained within biological fluid. The steps of the method include providing a micro-needle and electrochemical cell, inserting an open end of the micro-needle into the skin, transferring a sample of at least one target constituent into the

electrochemical cell, providing a first electrical signal to the cell, and receiving a second electrical signal generated by the cell. The second electrical signal is representative of the concentration of the constituent in the biological fluid. The electrochemical cell includes an outer electrode and an inner electrode, each of which is cylindrical and spaced from the other electrode in a co-axial relationship. Further, the micro-needle is formed at least partially by the outer electrode of the electrochemical cell. This arrangement is described, for example, in col. 8, lines 23-37 of the specification , and is illustrated in Figures 1a-1c.

In contrast, Uchigaki et al. teaches a lancet 52, which can also act as an electrode, wherein an axial core 52b of the lancet 52 acts as the active electrode, and the tube 52a, which surrounds the axial core 52b, can act as the counterpart electrode (see Figure 9 and col. 13, lines 12-30). As shown, the tube 52a is wrapped about the outer surface of the axial core 52b, and there is no suggestion in Uchigaki et al. that the outer and inner electrodes are spaced from each other in a co-axial relationship. In addition, there is no teaching or suggestion in Uchigaki et al. that its device could include a micro-needle that is formed by an outer electrode of its electrochemical cell, as in the present claim 40. That is, even if one were to take the position that the tube 52a that surrounds the axial core 52b of Figure 9 of Uchigaki et al. can be considered to be an outer electrode, such an electrode cannot be considered to form a part of a micro-needle of the device. In fact, the lancet 52 of Figure 9 is the only portion of the body fluid measuring apparatus that includes a pointed tip for use in penetrating the skin, and this lancet 52 could only be considered to be an *inner* electrode. For at least these reasons, claim 40 is believed to be patentable over Uchigaki et al.

With regard to the rejection of claims 58 and 59 (see rejection of claims 43 and 44), Applicants note that the sections of Uchigaki et al. referred to in the Office Action relative to the depth of puncturing the skin are too vague to anticipate the depth being "no greater than the viable epidermis" (claim 58) and "no greater than the stratum corneum" (claim 59). That is, the recognition of a puncturing depth that is "smaller than the conventional apparatus" or "smaller depth than is necessary", does not suggest the depths specified in the present claims 58 and 59. For this reason, and because claims 58 and 59

depend from claim 40, which is believed allowable, claims 58 and 59 are likewise believed to be allowable.

With regard to the rejection of claim 60 (see rejection of claim 45), the teaching of Uchigaki et al. of a hydrophilic high polymer layer as a part of its reactive layer 37 is not sufficient to anticipate the hydrophilic gel material of claim 61 that is both within a micro-needle lumen and in contact with an electrochemical cell. Further, Uchigaki et al. do not suggest that its hydrophilic polymer layer absorb a target constituent at an open end of a micro-needle (e.g., the area designated generally as 52d in Figure 9) in the manner recited in the present claim 60. For this reason, and because claim 60 depends from claim 40, which is believed allowable, claim 60 is likewise believed to be allowable.

With regard to the rejections of claims 61-64 and 66 (see rejections of claims 46-49 and 51), the teachings of Uchigaki et al. relative to an electronic circuit, display of measurement results, use of a microcomputer and other components, and the relative time frames for equilibrating a hydrophilic polymer layer are not sufficient to cure the deficiencies of its teachings relative to the methods of claim 40 discussed above. Thus, because claims 61-64 and 66 also depend from claim 40, which is believed to be allowable, these claims are likewise believed to be allowable.

Claim 65 (originally submitted as claim 50), was rejected under 35 U.S.C. §103(a) as being unpatentable over Uchigaki et al. in view of U.S. Patent No. 6,207,400 (Kwon et al.). The discussion in Kwon et al. of the use of a gel applied to a target surface and allowing sufficient time for the analyte from that target surface to equilibrate in the gel prior to a detection step does nothing to cure the deficiencies of Uchigaki et al. set out above relative to the structure of the electrochemical cell. Thus, claim 65, which depends from claim 40, which is believed allowable as discussed above, claim 65 is likewise believed allowable, at least in that it depends from claim 40.

Accordingly, it is submitted that presently pending claims 40, 42-51, and 58-66 are currently in condition for allowance, a notice of which is earnestly solicited. The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

The Commissioner is authorized to charge any additional fees or credit any overpayment to Kagan Binder deposit account No. 50-1775 and notify us of the same.

Respectfully Submitted,

Dated: 12/29/05 By

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